

Message

From: Subramaniam, Ravi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E738F9D27062486E9047184B867FD968-SUBRAMANIAM, RAVI]
Sent: 1/4/2018 5:18:39 PM
To: Bussard, David [Bussard.David@epa.gov]
Subject: RE: Next Steps on Formaldehyde IRIS Assessment - Rory

Yes, definitely. And, I forgot to add in my last note that, in response to the third paper we published, Rory published a letter to the editor that outlined his arguments to what we did (and we responded in the journal to that letter).

-

Ravi.

Ravi Subramaniam
(202) 564-2445 (O); Ex. 6 Personal Privacy (PP)
Off: RRB 51237 (T,W,Th); AWL (M,F). Mailcode 8602R

From: Bussard, David
Sent: Thursday, January 04, 2018 12:12 PM
To: Subramaniam, Ravi <Subramaniam.Ravi@epa.gov>
Subject: RE: Next Steps on Formaldehyde IRIS Assessment - Rory

Thanks!

So, while perhaps Rory never was asked for review comments on the draft assessment, he did get a chance to review the key arguments? Is that a fair summary?

David

From: Subramaniam, Ravi
Sent: Thursday, January 04, 2018 12:10 PM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>; Bussard, David <Bussard.David@epa.gov>
Cc: Thayer, Kris <thayer.kris@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Hagerthey, Scot <Hagerthey.Scot@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; White, Paul <White.Paul@epa.gov>
Subject: RE: Next Steps on Formaldehyde IRIS Assessment - Rory

(Including Paul White)

Rory reviewed 2 of the 3 papers we wrote on the nasal cancer modeling, and we addressed all of his comments. I do not think he reviewed any of our assessment sections. Rory Conolly, Julie Kimbell, and Fred Miller, from CIIT, were panel members on the expert consultation meeting we organized to get advice on next steps with using the CIIT model in EPA's assessment (held at NCEA, not at Hopkins). The other experts were Chris Portier and George Lucier, Kenny Crump, Linda Hanna, and Dale Hattis. We have a written report from Rory and others, as well as a summary, and all of these were included in the Appendix of the old assessment.

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Ravi.

Ravi Subramaniam
(202) 564-2445 (O), Ex. 6 Personal Privacy (PP) M
Off: RRB 51237 (T,W,Th); AWL (M,F). Mailcode 8602R

From: Bahadori, Tina
Sent: Wednesday, January 03, 2018 6:01 PM
To: Bussard, David <Bussard.David@epa.gov>
Cc: Thayer, Kris <thayer.kris@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Hagerthey, Scot <Hagerthey.Scot@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Subramaniam, Ravi <Subramaniam.Ravi@epa.gov>
Subject: RE: Next Steps on Formaldehyde IRIS Assessment - Rory

Thanks David. I neither want to 'allow' nor 'encourage' this 'infinite review/briefing' behavior. I just want to be prepared for every rabbit they pull out of their trick hats ☺. Thanks for this helpful answer.
T.

From: Bussard, David
Sent: Wednesday, January 3, 2018 5:57 PM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>
Cc: Thayer, Kris <thayer.kris@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Hagerthey, Scot <Hagerthey.Scot@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Subramaniam, Ravi <Subramaniam.Ravi@epa.gov>
Subject: Re: Next Steps on Formaldehyde IRIS Assessment - Rory

Tina

For your info, and we can nail this down if you need it....

Ravi or Paul or John Whalen might recall or have notes, but, I believe Rory was involved in a non-public workshop we held at Hopkins prior to 2011 that included George Lucier, Chris Portier, Fred Miller (from CIIT) and others.

In addition, John V may recall but I think Rory reviewed the 2011 external draft before it went to NAS.

I don't know that we have asked Rory to review this particular draft.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

David Bussard

On Jan 3, 2018, at 5:36 PM, Bahadori, Tina <Bahadori.Tina@epa.gov> wrote:

He was asking if Rory has reviewed how his work was cited or used in the assessment....I shut it down, but in case it comes up again want to know.

From: Thayer, Kris

Sent: Wednesday, January 3, 2018 5:36 PM

To: Bahadori, Tina <Bahadori.Tina@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>

Cc: Ross, Mary <Ross.Mary@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Hagerthey, Scot <Hagerthey.Scot@epa.gov>

Subject: RE: Next Steps on Formaldehyde IRIS Assessment

Rory was at the ACC workshop

From: Bahadori, Tina

Sent: Wednesday, January 3, 2018 10:27 PM

To: Bussard, David <Bussard.David@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>

Cc: Ross, Mary <Ross.Mary@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Hagerthey, Scot <Hagerthey.Scot@epa.gov>

Subject: FW: Next Steps on Formaldehyde IRIS Assessment

Hi Everyone,

Just a quick update....

- It appears that there is some renewed momentum to push this forward for Agency review. Fingers crossed.
 - o Your Swenberg-Andersen-Mundt talking points came in handy.
- But in a conversation with Yamada today he asked if 'Rory Conolly' had ever been asked to review the assessment. Who knows where this came from ☹, but how much interaction has there been with Rory?

Thanks,
T.

From: Bahadori, Tina

Sent: Tuesday, January 2, 2018 4:17 PM

To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>

Cc: Yamada, Richard (Yujiro) <yamada.richard@epa.gov>

Subject: RE: Next Steps on Formaldehyde IRIS Assessment

Dear Jennifer and Richard,

I hope you had a wonderful holiday. I wanted to follow up and see what the timeline for next steps might be for formaldehyde. As you know we have not yet begun Agency briefings or reviews and would like to do so as soon as possible.

Thanks,
Tina

From: Bahadori, Tina
Sent: Wednesday, December 20, 2017 8:39 AM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Cc: Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Subject: RE: Next Steps on Formaldehyde IRIS Assessment

Perfect, thank you. Let me know what I can do – ANYTHING ☺ -- to be helpful.
Tina

From: Orme-Zavaleta, Jennifer
Sent: Wednesday, December 20, 2017 8:19 AM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>
Cc: Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Subject: RE: Next Steps on Formaldehyde IRIS Assessment

Thanks Tina, Richard and I will be talking about next steps

Jennifer Orme-Zavaleta, PhD
Principal Deputy Assistant Administrator for Science
USEPA Office of Research and Development

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From: Bahadori, Tina
Sent: Wednesday, December 20, 2017 7:55 AM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Cc: Ross, Mary <Ross.Mary@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Ramasamy, Santhini <Ramasamy.Santhini@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>; Christian, Megan <Christian.Megan@epa.gov>; Kuhn, Kevin <Kuhn.Kevin@epa.gov>; Fleming, Megan <Fleming.Megan@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>
Subject: Next Steps on Formaldehyde IRIS Assessment

Good Morning Jennifer and Richard,

I wanted to follow up on the path forward for formaldehyde. OMB is requesting that the IRIS Report to Congress provide an update on the timeline of this assessment.

As you know, the formaldehyde assessment is ready to advance for Agency Review – a step in the IRIS process that is normally routine and does not require internal clearances. This is the first IRIS assessment that fully incorporates the NAS 2011 recommendations on systematic review and clear and transparent presentation of evidence in the assessment. In addition, to address the issue of the length of the assessment, an overview document (<140 pages, mostly graphs and tables) has been developed that fully represents the assessment. This overview will be accompanied by the full assessment and appendices. Also, following earlier IOAA reviews, the assessment team has taken the quantitation of leukemia risk out of the cancer unit risk values. Instead, they will ask the NAS peer reviewers to evaluate their approach to leukemia and recommend a path forward.

Since we last briefed the IOAA on December 4th, we have gone through the assessment and made sure we had considered and where possible attended to the issues that ACC consultants - led by Drs. Mundt, Andersen, and Swenberg - raised when they briefed Jennifer last week. The challenge, of course, is that outside of the public comment process, there is no opportunity for us to respond to or allay the concerns raised by stakeholders. For your reference, the assessment team developed some high level talking points – attached here -- that signal how the issues were considered in the assessment; as can be expected, there are counter arguments supported by the human evidence.

Finally, the hazard evaluation in this assessment is scientifically consistent with evaluations done by other authoritative bodies, including the National Toxicology Program. But there is no way to settle the debate other than allowing this assessment to undergo the extensive and sequential IRIS process - Agency Review, Interagency Review, Public Comment, and Peer Review. The NAS has already been funded to conduct this review out of our FY17 appropriations, and their Peer Review step includes further opportunities for public comment.

Next Steps: The assessment team is prepared to begin the Agency briefings and review in January, assuming you give the signal. As requested by the Administrator, we are also prepared to set up secure environments where Agency reviewers can come in and review hard copies of the document. If we begin Agency Review in January, our plan was to transmit the document to the NAS in September 2018 for peer review. We would need to give advance notice to them so they can assemble the committee.

We look forward to hearing back from you.

Tina

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Tina Bahadori, Sc.D.
Director, National Center for Environmental Assessment (EPA/ORD/NCEA)
National Program Director, Human Health Risk Assessment (EPA/ORD/HHRA)
RRB Room 71210; Telephone: 202-564-7903; Mobile: 202-680-8771

From: Bahadori, Tina
Sent: Thursday, December 7, 2017 8:16 AM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Subject: formaldehyde

Good morning Jennifer and Richard,

Just checking to see if you have an update on path forward for formaldehyde? We would like to at least schedule the 'oral' Agency briefing. It is hard to get on calendars.

Thanks,
Tina